

1090276

510(k) Summary

Sponsor: Siemens Medical Solutions, Inc.,
Ultrasound Division
1230 Shorebird Way
Mountain View, California 94043

FEB 19 2009

Contact Person: Shelly Pearce
Telephone: (650) 694-5988
Fax: (650) 694-5580

Submission Date: January 6, 2009

Device Name: ACUSON X300™ Diagnostic Ultrasound System
SONOVISTA X300 Diagnostic Ultrasound System
ACUSON X300™ Diagnostic Ultrasound System, premium edition

Common Name: Diagnostic Ultrasound System with Accessories

Classification:

Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology

Ultrasonic Pulsed Doppler Imaging System	FR # 892.1550	Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System	FR # 892.1560	Product Code 90-IYO
Diagnostic Ultrasound Transducer	FR # 892.1570	Product Code 90-ITX
Diagnostic Intravascular Catheter	FR # 870.1200	Product Code 74-DQO

A. Legally Marketed Predicate Devices

The Siemens Acuson X300 ultrasound system is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to our current product, the Siemens Acuson X300 ultrasound system (K080760, K072676, K071036 and K061946) and the following:

- K050240, ACUSON CV70 Cardiovascular System
- K063085, ACUSON Sequoia Ultrasound System
- K071036, Acuson X300 Diagnostic Ultrasound System
- K080760, ACUSON X300™ Diagnostic Ultrasound System, premium edition
- K083149, Arterial Health Package (AHP) software

B. Device Description:

The Acuson X300 has been designed to meet the following product safety standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment

- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
 - EN/IEC 60601-1
 - EN/IEC 60601-1-1
 - EN/IEC 60601-1-2
 - EN/IEC 60601-1-4
 - EN/IEC 60601-1-6
 - EN/IEC 60601-2-18
 - EN/IEC 60601-2-25
- IEC 1157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

C. Intended Use

The Siemens Acuson X300 ultrasound imaging system is intended for the following applications: General Radiology, Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Neonatal/Adult Cephalic, Cardiac, Transesophageal, Pelvic, Transcranial, OB/GYN, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

D. Substantial Equivalence

The submission device is substantially equivalent to the predicate with regard to both intended use and technological characteristics.

E. Performance Data

The Acuson X300 modifications are verified and validated according to the company's design control process.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Siemens Medical Solutions USA, Inc., Ultrasound Group
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

FEB 19 2009

Re: K090276

Trade/Device Name: Acuson X300 Diagnostic Ultrasound Systems
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, IYN, and ITX
Dated: February 3, 2009
Received: February 4, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Acuson X300 Diagnostic Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

P4-2 Phased Sector Array

CH5-2 Convex Array

VF10-5 Linear Array

L9-5 Linear Array

EC9-4 Convex Array

EV9-4 Convex Array

VF13-5 Linear Array
P8-4 Phased Sector Array
BE 9-4 Convex Array
CW2 Continuous Wave
CW5 Continuous Wave
AcuNav 8F Intracardiac
AcuNav 10F Intracardiac
V5Ms TEE
4V1c Phased Sector Array
VF13-5SP Linear Array
C8-5 Tightly Curved Array
8L3 Linear "Regel"
10V4 Phased Array
G7F2 Curved Array Mechanical 3D/4D
EV9F4 Curved Array Mechanical 3D/4D
L13F5 3D/4D Mechanical Wobbler Linear
VF8-3 Linear Array
P5-1 Phased Array
C6-2 Convex Array
SoundStar 10F
P9-4 Phased Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

If you have any questions regarding the content of this letter, please contact Paul Hardy at (240) 276-3666.

Sincerely yours,



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Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use Statement

510(k) Number (if known): K090276

Device Name: Acuson X300 Diagnostic Ultrasound System

Indications For Use:

The Siemens Acuson X300 ultrasound imaging system is intended for the following applications: General Radiology, Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Neonatal/Adult Cephalic, Cardiac, Transesophageal, Pelvic, Transcranial, OB/GYN, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K090276

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:
Intended Use:

ACUSON X300 Diagnostic Ultrasound Systems
Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Neuro)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-rectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-vaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-urethral										
	Trans-esoph. (non-Card.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Convent.)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superficial)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
Cardiac	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11,12
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-esophageal (Cardiac)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-Cardiac		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
Peripheral Vessel	Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11,12
	Other (Specify)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D Imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging
- Note 8 SieClear multi-view spatial compounding
- Note 9 Tissue Equalization Technology
- Note 10 Intracardiac imaging
- Note 11 Dynamic TCE
- Note 12 AHP

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K090276

Diagnostic Ultrasound Indications for Use Form

510(k) Number (If known):

Device Name:

**P4-2 Phased Sector Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 11 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,5,6,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)										
	Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

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- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging
- Note 8 SieClear multi-view spatial compounding
- Note 9 Tissue Equalization Technology
- Note 10 Intracardiac imaging
- Note 11 Dynamic TCE

[Signature] (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K09276

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

CH5-2 Convex Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic.)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

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- Note 2 Ensemble tissue harmonic imaging
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- Note 7 Contrast agent imaging
- Note 8 SieClear multi-view spatial compounding
- Note 9 Tissue Equalization Technology
- Note 10 Intracardiac imaging
- Note 11 Dynamic TCE

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Concurrence of CD RH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

[Signature]
(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number: K080760

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

VF10-5 Linear Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										Note 12
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11,12
	Other (Specify)										

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- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 2 Ensemble tissue harmonic imaging
 Note 3 3D imaging
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 Note 5 Power SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 7 Contrast agent imaging
 Note 8 SieClear multi-view spatial compounding
 Note 9 Tissue Equalization Technology
 Note 10 Intracardiac imaging
 Note 11 Dynamic TCE

Note 12 AHP

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K090276

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

L9-5 Linear Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superf.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										Note 12
	Intra-vascular (Cardiac)										
	Trans-catheter (Cardiac)										
	Intra-Cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11,12
	Other (Specify)										

N = new indication; P = previously cleared by K080760

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K09076

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

EC9-4 Convex Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 11 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal										
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-vaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-Cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel										
	Other (Specify)										

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 2 Ensemble tissue harmonic imaging
 Note 3 3D Imaging
 Note 4 B&W SieScape panoramic imaging
 Note 5 Power SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 7 Contrast agent imaging
 Note 8 SieClear multi-view spatial compounding
 Note 9 Tissue Equalization Technology
 Note 10 Intracardiac Imaging
 Note 11 Dynamic TCE

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 Conformance of CDRH, Office of Device Evaluation (ODE)
 Prescription Use (Per 21 CFR 801.109)
 (Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K090276

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

EV9-4 Convex Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 11 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal										
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-vaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-Cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel										
	Other (Specify)										

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 2 Ensemble tissue harmonic imaging
 Note 3 3D imaging
 Note 4 B&W SieScape panoramic imaging
 Note 5 Power SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 7 Contrast agent imaging
 Note 8 SieClear multi-view spatial compounding
 Note 9 Tissue Equalization Technology
 Note 10 Intracardiac imaging
 Note 11 Dynamic TCE

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 Division of Reproductive, Abdominal and Radiological Devices
 510(k) Number K09076

Conformance of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

VF13-5 Linear Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 8)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
Cardiac	Intra-vascular										
	Other (Specify)										
	Cardiac Adult										Note 12
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
Peripheral Vessel	Intra-cardiac										
	Other (Specify)										
Peripheral	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11,12
Vessel	Other (Specify)										

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 2 Ensemble tissue harmonic imaging
 Note 3 3D imaging
 Note 4 B&W SieScape panoramic imaging
 Note 5 Power SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 7 Contrast agent imaging
 Note 8 SieClear multi-view spatial compounding
 Note 9 Tissue Equalization Technology
 Note 10 Intracardiac imaging
 Note 11 Dynamic TCE
 Note 12 AHP

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K09076

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

P8-4 Phased Sector Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,5,6,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)										
	Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superficial)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D Imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging
- Note 8 SieClear multi-view spatial compounding
- Note 9 Tissue Equalization Technology
- Note 10 Intracardiac imaging
- Note 11 Dynamic TCE

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Concurrence of CD RH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K090276

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

**BE 9-4 Convex Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 11 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Abdominal										
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Adult Cephalic										
	Trans-rectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Trans-vaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic.)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
Peripheral Vessel	Other (Specify)										
	Peripheral vessel										
	Other (Specify)										

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 2 Ensemble tissue harmonic imaging
 Note 3 3D Imaging
 Note 4 B&W SieScape panoramic imaging
 Note 5 Power SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 7 Contrast agent imaging
 Note 8 SieClear multi-view spatial compounding
 Note 9 Tissue Equalization Technology
 Note 10 Intracardiac Imaging
 Note 11 Dynamic TCE

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K090276

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

CW2 Continuous Wave Doppler Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal					P					
	Abdominal					P					
	Intra-operative (Note 6)					P					
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric					P					
	Small Organ (Note 1)					P					
	Neonatal Cephalic					P					
	Adult Cephalic					P					
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)					P					
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult					P					
	Cardiac Pediatric					P					
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral	Peripheral vessel					P					
Vessel	Other (Specify)										

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging
- Note 8 SieClear multi-view spatial compounding
- Note 9 Tissue Equalization Technology
- Note 10 Intracardiac imaging
- Note 11 Dynamic TCE

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

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(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K090276

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

CW5 Continuous Wave Doppler Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal (Imaging & Other)	Fetal					P					
	Abdominal					P					
	Intra-operative (Note 6)					P					
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric					P					
	Small Organ (Note 1)					P					
	Neonatal Cephalic					P					
	Adult Cephalic					P					
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent)					P					
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult					P					
	Cardiac Pediatric					P					
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-Cardiac										
Peripheral Vessel	Other (Specify)										
	Peripheral vessel					P					
	Other (Specify)										

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 2 Ensemble tissue harmonic imaging
 Note 3 3D imaging
 Note 4 B&W SieScape panoramic imaging
 Note 5 Power SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 7 Contrast agent imaging
 Note 8 SieClear multi-view spatial compounding
 Note 9 Tissue Equalization Technology
 Note 10 Intracardiac imaging
 Note 11 Dynamic TCE

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K090276

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

AcuNav 8F Intracardiac Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal										
	Abdominal										
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Small Organ (Note 1)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic.)										
	Intra-vascular		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Intra-vascular (Cardiac)		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Trans-esophageal (Cardiac)										
	Intra-cardiac		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Other (Specify)										
Peripheral Vessel	Peripheral vessel										
	Other (Specify)										

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging
- Note 8 SieClear multi-view spatial compounding
- Note 9 Tissue Equalization Technology
- Note 10 Intracardiac imaging
- Note 11 Dynamic TCE

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K090276

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

AcuNav 10F Intracardiac Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal										
	Abdominal										
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Small Organ (Note 1)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic)										
	Intra-vascular		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Intra-vascular (Cardiac)		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Trans-esophageal (Cardiac)										
	Intra-cardiac		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Other (Specify)										
Peripheral Vessel	Peripheral vessel										
	Other (Specify)										

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 2 Ensemble tissue harmonic imaging
 Note 3 3D Imaging
 Note 4 B&W SieScape panoramic imaging
 Note 5 Power SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 7 Contrast agent imaging
 Note 8 SieClear multi-view spatial compounding
 Note 9 Tissue Equalization Technology
 Note 10 Intracardiac imaging
 Note 11 Dynamic-TCE

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 Prescription Use (Per 21 CFR 801.109)
 (Division Sign-Off)
 Division of Reproductive, Abdominal and Radiological Devices
 510(k) Number K090276

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

V5Ms TEE Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal										
	Abdominal										
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	Small Organ (Note 1)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,11
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,11
	Intra-cardiac										
Peripheral Vessel	Peripheral vessel										
	Other (Specify)										

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 2 Ensemble tissue harmonic imaging
 Note 3 3D imaging
 Note 4 B&W SieScape panoramic imaging
 Note 5 Power SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 7 Contrast agent imaging
 Note 8 SieClear multi-view spatial compounding
 Note 9 Tissue Equalization Technology
 Note 10 Intracardiac Imaging
 Note 11 Dynamic TCE

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Concurrence of CDH, Office of Device Evaluation (ODE)
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Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K090276

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

4V1c Phased Sector Array Transducer for use with:

ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 11 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,5,6,7,8,9
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Small Organ (Note 1)										
	Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic.)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
Peripheral Vessel	Other (Specify)										
	Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Other (Specify)										

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging
- Note 8 SieClear multi-view spatial compounding
- Note 9 Tissue Equalization Technology
- Note 10 Intracardiac Imaging
- Note 11 Dynamic TCE

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K09276

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

VF13-5SP Linear Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal										
	Abdominal										
	Intra-operative (Note 6)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Neuro)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superficial)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										Note 12
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11,12
	Other (Specify)										

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 2 Ensemble tissue harmonic imaging
 Note 3 3D Imaging
 Note 4 B&W SieScape panoramic imaging
 Note 5 Power SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 7 Contrast agent imaging
 Note 8 SieClear multi-view spatial compounding
 Note 9 Tissue Equalization Technology
 Note 10 Intracardiac Imaging
 Note 11 Dynamic TCE
 Note 12 AHP

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 (Division Sign-Off) _____
 Division of Reproductive, Abdominal and Radiological Devices
 510(k) Number K090276

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

**C8-5 Tightly Curved Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 11 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-operative (Note 2)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Adult Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Musculo-skel. (Superf.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Cardiac Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Other (Specify)										

N = new indication; P = previously cleared by K080780

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 2 Ensemble tissue harmonic imaging
 Note 3 3D imaging
 Note 4 B&W SieScape panoramic imaging
 Note 5 Power SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 7 Contrast agent imaging
 Note 8 SieClear multi-view spatial compounding
 Note 9 Tissue Equalization Technology
 Note 10 Intracardiac imaging
 Note 11 Dynamic TCE

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Concurrence of CDRI, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K090276

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

8L3 Linear "Regel" Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Musculo-skel. (Superfic)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										Note 12
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,12
	Other (Specify)										

N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 3D Imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 SieClear multi-view spatial compounding

Note 9 Tissue Equalization Technology

Note 10 Intracardiac imaging


Note 11 Dynamic TCE

Note 12 AHP

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K09076

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

**10V4 Phased Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Small Organ (Note 1)										
	Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Musculo-skel. (Superficial)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Other (Specify)										

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 2 Ensemble tissue harmonic imaging
 Note 3 3D Imaging
 Note 4 B&W SieScape panoramic Imaging
 Note 5 Power SieScape panoramic Imaging
 Note 6 For example: abdominal, vascular
 Note 7 Contrast agent Imaging
 Note 8 SieClear multi-view spatial compounding
 Note 9 Tissue Equalization Technology
 Note 10 Intracardiac imaging
 Note 11 Dynamic TCE

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K090276

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

C7F2 Curved Array Mechanical 3D/4D Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 2 Ensemble tissue harmonic imaging
 Note 3 3D Imaging
 Note 4 B&W SieScape panoramic imaging
 Note 5 Power SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 7 Contrast agent imaging
 Note 8 SieClear multi-view spatial compounding
 Note 9 Tissue Equalization Technology
 Note 10 Intracardiac imaging
 Note 11 Dynamic TCE

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 Concurrence of CDRH, Office of Device Evaluation (ODE)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K09276

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

EV9F4 Curved Array Mechanical 3D/4D Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal										
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-vaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel										
	Other (Specify)										

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging
- Note 8 SieClear multi-view spatial compounding
- Note 9 Tissue Equalization Technology
- Note 10 Intracardiac Imaging
- Note 11 Dynamic TCE

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number 1C0 90276

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

**L13F5 3D/4D Mechanical Wobbler Linear Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Musculo-skel. (Superfic)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		*P	P	*P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Other (Specify)										

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D Imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging
- Note 8 SieClear multi-view spatial compounding
- Note 9 Tissue Equalization Technology
- Note 10 Intracardiac imaging
- Note 11 Dynamic TCE

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K0 90276

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

VF8-3 Linear Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 11 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 5)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superficial)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										Note 12
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11,12
	Other (Specify)										

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 2 Ensemble tissue harmonic imaging
 Note 3 3D Imaging
 Note 4 B&W SieScape panoramic imaging
 Note 5 Power SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 7 Contrast agent imaging
 Note 8 SieClear multi-view spatial compounding
 Note 9 Tissue Equalization Technology
 Note 10 Intracardiac imaging
 Note 11 Dynamic TCE
 Note 12 AHP

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number 1090276

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

**P5-1 Phased Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)										
	Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 2 Ensemble tissue harmonic imaging
 Note 3 3D imaging
 Note 4 B&W SieScape panoramic imaging
 Note 5 Power SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 7 Contrast agent imaging
 Note 8 SieClear multi-view spatial compounding
 Note 9 Tissue Equalization Technology
 Note 10 Intracardiac imaging
 Note 11 Dynamic TCE

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K090276

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

C6-2 Convex Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 11 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic.)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 2 Ensemble tissue harmonic imaging
 Note 3 3D imaging
 Note 4 B&W SieScape panoramic imaging
 Note 5 Power SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 7 Contrast agent imaging
 Note 8 SieClear multi-view spatial compounding
 Note 9 Tissue Equalization Technology
 Note 10 Intracardiac imaging
 Note 11 Dynamic TCE

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Concurrence of CDRH, Office of Device Evaluation (ODE)
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Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K090276

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

SoundStar 10F Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 11 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal										
	Abdominal										
	Intra-operative (Note 8)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	Small Organ (Note 1)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic)										
	Intra-vascular		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Intra-vascular (Cardiac)		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Trans-esophageal (Cardiac)										
	Intra-cardiac		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Other (Specify)										
Peripheral Vessel	Peripheral vessel										
	Other (Specify)										

N = new indication; P = previously cleared by K080760;

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 2 Ensemble tissue harmonic imaging
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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K090276

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

P9-4 Phased Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		N	N	N	N	N	N		BMDC	Note 2,3,5,6,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8,9,11
	Laparoscopic										
	Pediatric		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superficial)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
Peripheral Vessel	Other (Cardiac Neonatal)		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,9,11
	Peripheral vessel		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

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- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
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